

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: :
SHANLER et al. : Confirmation No.: 4999
Application No.: 10/763,807 : Group Art Unit: 1627
Filed: January 22, 2004 : Examiner: Carter, Kendra D.

**TITLE: METHOD AND THERAPEUTIC/COSMETIC TOPICAL COMPOSITIONS FOR
THE TREATMENT OF ROSACEA AND SKIN ERYTHEMA USING A1-
ADRENOCEPTOR AGONISTS**

Mail Stop Petition
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

APPLICATION FOR PATENT TERM ADJUSTMENT

PURSUANT TO 37 CFR §1.705(b)

Dear Sir:

In accordance with the provisions of 37 C.F.R. §1.705(b), Applicant respectfully requests that the Patent Term Adjustment (PTA) calculated by the U.S. Patent and Trademark Office (PTO) in the above-referenced application be reconsidered. We have received a Notice of Allowance in this application and are filing this petition concurrently with payment of the issue fee. The Notice of Allowance indicates that this application is entitled to seven hundred and twenty-eight (728) days of Patent Term Adjustment. *See* Exhibit A. This is based on the PTO's calculations of specific delays of the Applicant and the PTO as reflected in the patent term adjustment history IFW page. *See* Exhibit B. The Notice of Allowance in the above-referenced application provides an estimated patent issue date of November 23, 2010. For the reasons set forth below, Applicant believes that it is entitled to a total patent term adjustment of one thousand five hundred and forty-eight (1548) days.

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Applicant calculates the “A delay”¹ to be nine hundred thirty-six (936) days, the “B delay”² to be nine hundred sixty-nine (969) days, and the overlap³ of “A delay” and “B delay” to be two hundred sixty-five (265) days. There is no “C delay.”⁴ Applicant’s delay in this case is ninety two (92) days. This brings the total patent term adjustment,⁵ to which Applicant is entitled, to one thousand five hundred forty-eight (1548) days ($936 + 969 - 265 - 92 = 1548$).

In support of this request, Applicant submits the following information:

Filing Date:	01-22-2004
Third Anniversary of Pendency:	01-22-2007
Date of Filing of RCE	09-17-2009
Notice of Allowance date	05-14-2010

Based on the above information, Applicant calculates the Patent Term Adjustment as follows:

A delay calculation	Day after the 14 month date after the date on which application was filed (03-22-2005) and date when the <u>Restriction Requirement</u> was mailed (06-20-2007)	820 days
	Day after 4 month date after the date on which the Response to Office Action was filed (01-11-2008) and date when an <u>Office Action</u> was mailed (09-04-2008)	116 days

¹ “A delays” are defined as delays by the PTO under 35 U.S.C. § 154(b)(1)(A), which guarantees prompt PTO response.

² “B delays” are defined as delays by the PTO under 35 U.S.C. § 154(b)(1)(B), which guarantees no more than three year application pendency.

³ To the extent that the periods of delay overlap, the period of any term adjustment shall not exceed the actual number of days the issuance of the patent was delayed. See 35 U.S.C. § 154(b)(2)(A). As outlined in *Wyeth v. Dudas*, 580 F. Supp. 2d 138 (D.D.C. 2008), aff’d *Wyeth v. Kappos*, Fed. Cir. 2009-1120, decided January 7, 2010, the only way that these periods of time can “overlap” is if they occur on the same day. If an “A delay” occurs on one calendar day and a “B delay” occurs on another calendar day, they do not overlap and 35 U.S.C. § 154(b)(2)(A) does not limit the extension of the patent term to one day. *Id.* The Federal Circuit reasoned that “the language of section 154(b) does not even permit B delay to start running until three years after the application is filed” and thus overlap cannot occur before the end of the three year pendency period. *Wyeth v. Kappos* at *8.

⁴ “C delays” are defined as delays by the PTO under 35 U.S.C. § 154(c), which extends patent term for delays caused by interferences, secrecy orders and appeals.

⁵ The Patentees’ delay is subtracted from the PTO delay (calculated by the addition of A delay, B delay and C delay) to produce the total patent term adjustment.

B delay calculation	Day after Third Anniversary (01-22-2007) and <u>RCE</u> filing date (09-17-2009)	969 days
Overlap of A delay and B delay	Day after Third Anniversary (01-22-2007) and date when Restriction Requirement was filed (06-20-2007)	149 days
	Day after 4 month date after the date on which the Response to Office Action was filed (01-11-2008) and mailing of <u>Non-Final Office Action</u> (09-04-2008)	116 days
Applicant delay calculation	Day after 3 month date after the date on which a notice or action was mailed (06-17-2009) and ending on the date the reply was filed (09-17-2009).	92 days

This application is not subject to a terminal disclaimer.

Applicant is therefore entitled to a patent term adjustment of one thousand five hundred and forty-eight (1548) days. Applicant's calculation of the patent term adjustment is based on the projection that this patent will issue on the Tuesday before the date that is 28 weeks after the mailing date of the Notice of Allowance which is November 23, 2010 and Applicant reserves the right to petition for any further patent term adjustment after the patent issues.

In consideration of the information described above, Applicant believes that the Patent PTO's PTA calculation of seven hundred twenty-eight (728) days is incorrect. As such, Applicant respectfully requests reconsideration of the PTA in the following manner:

1. total PTO delay should be calculated as 1640 days (i.e., the sum of 936 days of "A delay," 969 days of "B delay," and 0 days of "C delay" minus the 265 days of overlap);
2. total Applicant Delay should be calculated as 92 days; and
3. total PTA should be calculated as 1548 days.

AUTHORIZATION

The Commissioner is hereby authorized to charge any fees which may be required for this paper, or credit any overpayment, to Deposit Account No. 50-0436.

Respectfully submitted,

A handwritten signature in dark ink, appearing to read "N. Nicole Endejann", written over a horizontal line.

N. Nicole Endejann
Reg. No. 50,229

Pepper Hamilton LLP
BNY Mellon Center, 50th Floor
500 Grant Street
Pittsburgh, PA 15219
Telephone: 412.454.5869
Facsimile: 412.281.0717
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